Potential Effects of Proposed Children's Health and Medicare Protection Act

On August 1, the U.S. House of Representative passed HR 3162, the Children's Health and Medicare Protection (CHAMP) Act of 2007. The CHAMP Act reauthorizes the State Children's Health Insurance Program and provides health insurance coverage to millions of uninsured children; however, the bill contains several provisions that could be detrimental to the future of imaging.

The August issue of the *SNM Health Policy and Regulatory Affairs Newsletter* and a press release issued by SNM on August 29 ("SNM: Vital Medical Imaging Needs To Be Protected"), both available online at www.snm.org, detail the specific areas of concern.

Through the Access to Medical Imaging Coalition, the SNM sent letters to Speaker of the House Nancy Pelosi (D-CA) and others within the Democratic leadership urging Congress to amend the CHAMP Act, particularly section 309, to protect vital medical imaging services. Section 309 directs the Centers for Medicare & Medicaid Services to increase its assumption on the amount of time imaging equipment is used from 50% to 70%. This will effectively lower the cost per unit for imaging services and reduce Medicare payments. A "Dear Colleague" letter is also being circulated among members of the House and Senate.

At this time, the future of this legislation is unclear. The Senate version of the bill only addresses the state children's health insurance plans and does not contain any Medicare provisions. The House and Senate are currently working on reconciling their versions, with hopes of passing this legislation when they return in September. The president has stated numerous times that he will veto the bill.

The American Medical Association (AMA) supports the CHAMP Act but has publicly stated that they are aware of the negative impact the bill could have on imaging. In an advocacy letter recently sent to specialty executive vice presidents, the AMA stated that one of its priorities for the House/Senate conference negotiations will include "opposing additional cuts for imaging services."

SNM Leaders Meet With FDA Commissioner

On July 30, the SNM executive leadership and staff met with U.S. Food and Drug Administration (FDA) Commissioner Andrew C. von Eschenbach, MD, and FDA Center for Drug Evaluation and Research (CDER) representatives.

Hugh Cannon

At the meeting SNM leaders discussed the need for FDA to acquire additional personnel with molecular imaging experience in the CDER Division of Medical Imaging and Hematology Products, requested the reinstatement of the Medical Imaging Drug Advisory Committee, and introduced draft concepts and potential strategies for advancing emerging molecular imaging technologies.

After the meeting, SNM posted an FDA advertisement for "imaging science physicians" (civil service salary at the GS-14 level) in the SNM online Career Center and also published the advertisement in the September issue of *The Journal of Nuclear Medicine*. SNM encourages physicians interested in civil service to explore this opportunity.

NRC Part 35 Training and Experience Requirements

The U.S. Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI) met June 12–13 in Rockville, MD. The highlight of the meeting was an open discussion on the implementation of 10 CFR Part 35 Training and Experience (T&E) requirements. Most relevant professional associations and certification boards were represented.

At the meeting, SNM representative Terence Beven, MD (former ACNP/SNM Joint Government Relations Committee chair), presented the nuclear medicine view on implementation of T&E requirements. SNM:

- Supported the removal of the preceptor statement for the board certification pathway;
- Called for the review of the effective date concept;
- Requested clarification on what is required of physicians who completed their residency 7 years prior and then applied for authorized user status;
- Called into question the 200 hours of classroom and laboratory training required by 10 CFR 35.390;
- Stated that certification boards should determine the acceptable training methods for the education of physicians regarding activities such as eluting the generator system, performing the measuring and testing of the

eluate, processing the eluate with reagent kits to prepare radioactive drugs, and administering radioactive agents;
- Asked for a defined pathway by which a Canadian nuclear medicine physician could meet the new T&E criteria without necessarily being trained by an NRC-licensed authorized user; and
- Suggested that Canadian physicians should have their training verified by an authorized user in the United States and that they should also be required to take a few hours of additional training to confirm they are knowledgeable about NRC regulations.

ACMUI members discussed potential resolutions for the various T&E related concerns brought up by the public but unfortunately needed to adjourn the meeting before the completion of business. This issue was also the subject of a follow-up ACMUI teleconference on August 16, but, again, a portion of the agenda was tabled because of time constraints. SNM anticipates that ACMUI will finish T&E business at its regularly scheduled fall meeting, unless the NRC plans to hold an additional follow-up teleconference in the interim.

NRC NARM Rulemaking Update

As part of the naturally occurring and accelerator-produced radioactive material (NARM) rulemaking effort, the NRC evaluated the need to revise their licensing guidance documents to provide updated information incorporating the newly covered byproduct material. Two NUREG-1556 documents are being revised to provide additional guidance to licensees: NUREG-1556, Volume 13, Revision 1, *Consolidated Guidance About Materials License—Program-Specific Guidance About Commercial Radiopharmacy Licenses*, and NUREG-1556, Volume 9, Revision 2, *Consolidated Guidance About Materials Licenses—Program-Specific Guidance About Medical Use Licenses*. In addition, a new NUREG-1556 volume was created (as Volume 21) to address production of radioactive material using an accelerator, entitled, *Consolidated Guidance About Materials Licenses—Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator.*

These guidance documents were announced on the SNM Web site (www.snm.org> GOVERNMENT RELATIONS) and can also be accessed via the "NARM Toolbox" section of the NRC Web site (http://nrc-stp.ornl.gov/narmtoolbox/narmguidance.html).

GE Healthcare Ceretec® Supply

GE Healthcare released a letter to customers informing them of an imminent shortage of their Ceretec (^{99m}Tc-exametazime) product. One of their manufacturing sites, located in Gloucester, UK, had to close because of flooding, thus Ceretec will be off the market as soon as current inventory levels have been exhausted.

GE Healthcare has stated that it is committed to restoring operations at the Gloucester manufacturing site as soon as possible and that significant resources have been deployed to assist in the project. However, they expect the interruption to last several months.

The GE Healthcare letter to customers is posted on the SNM Web site at http://interactive.snm.org/index.cfm?PageID=6666.

Hugh Cannon
Director, Health Policy and Regulator Affairs, SNM

(Continued from page 20N)
provide on physiology, biologic structure, metabolism, and cellular and molecular processes. The Frontiers conference was intended to address these needs, and the consensus of the attendees was that the meeting met its objectives and was a valuable addition to the calendar of meetings.

Todd E. Peterson, PhD
Vanderbilt University Medical Center
Nashville, TN

(Continued from page 20N)
medicine, general nuclear medicine, and radionuclide therapy.

Other practice accreditation organizations, such as the Intersocietal Commission for the Accreditation of Nuclear Medicine Laboratories, have begun developing practice performance measures. In the future, it is likely that these organizations will develop standards for physician-level measures of practice performance, such as clarity and timeliness of reports. An essential component of CQI is to provide feedback on how an individual's practice compares with peers, so that he or she can then develop an improvement plan (as needed) and then remeasure practice performance.

Henry D. Royal, MD
Executive Director
American Board of Nuclear Medicine